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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,370	01/23/2001	Jeffrey Browning	A054 US	2716

7590

12/28/2004

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/767,370	<b>Applicant(s)</b> BROWNING ET AL.	
	<b>Examiner</b> Christopher H Yaen	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 8,10,11,16,26,28,29 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8,10,11,16,26,28,29 and 37-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

**Re: Browning *et al***

**Priority Date: 17 December 1998**

1. The amendment filed 9/27/2004 is acknowledged and entered into the record. Accordingly, claims 1-7,9,12-15,17-25, 27, and 30-36 are canceled without prejudice or disclaimer, and claims 40-42 are newly added.
2. Claims 8,10-11,16,26,28-29, and 37-42 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 102***

4. The rejection of claims 8,10,26-28,39 and now newly added claims 40 and 42 under 35 USC § 102(b) as being anticipated by Crowe *et al* (Science 1994; 264:707 – herein Crowe-Science) is maintained for the reasons of record. Applicant argues that the instant invention is not drawn to a product per se, but rather to a “preparation”. Applicant substantiates their arguments by indicating that the preparation differs from that of Crowe-Science because the process of making the preparation produces a physically different substance. Applicant discusses in detail that at lower temperatures (i.e. 27°C-35°C), the preparation prepared produces 70% or more of “biologically active” LT-beta-R-Ig fusion protein. In contrast, applicant argues that Crowe-Science only produces about 50% biologically active molecules (see page 10, last paragraph). Applicant’s arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. For the purposes of examination, the term

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“preparation” as currently amended is interpreted as being a product as opposed to a method of making. Furthermore, applicant is reminded that an examination on the merits has been performed on a product and not a method. With respect to the arguments set forth by the applicant, products that are claimed as product-by-process can be distinguished over the prior art only if the product that is produced by that specific process imparts structurally distinct characteristics (see e.g. *In re Gamero*). In the instant case applicant has only argued that the final product is more “active”, of which the specification has defined as being capable of binding to a ligand (see page 9, lines 7-8). Crowe-Science teaches that the fusion product made at higher temperatures (i.e. 37°C) is active because it was capable of binding ligand (see pg 706 1<sup>st</sup> full paragraph). Therefore despite applicant’s assertions, the product disclosed by Crowe-Science is active and therefore structurally similar to that of the instant invention. Therefore, the process of making the product in this case does not impart any structurally distinct characteristics that would help distinguish this product over that of the prior art.

It is noted that MPEP 2113 teaches that the product does not depend on the method of production, therefore, newly added claims 40 and 42 do not provide limitations that are deemed patentably distinct because the claims are drawn to means of production or a process.

Therefore, the rejection of claims under 35 USC 102(b) as being anticipated by Crowe *et al* is maintained for the reasons of record.

***Claim Rejections - 35 USC § 102***

5. The rejection of claims 8,11,26,29, 37-39, and now newly added claims 40 and 42 under 35 USC § 102 as being anticipated by Kwon *et al* (J. Biol. Chem. 1997; 272:14272-14276) is maintained for the reasons of record. Applicant's arguments are substantially similar to those already presented and argued (see paragraph 4 above). Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. For the purposes of examination, the term "preparation" as currently amended is interpreted as being a product as opposed to a method of making. Furthermore, applicant is reminded that an examination on the merits has been performed on a product and not a method. Again, the product taught by Kwon *et al* appears to have the same activity of the instant product (i.e. ability to bind to a ligand) and therefore the claim limitations drawn to means of preparing the product do not necessarily impart any structurally distinct characteristics onto the product claimed.

It is noted that MPEP 2113 teaches that the product does not depend on the method of production, therefore, newly added claims 40 and 42 do not provide limitations that are deemed patentably distinct because these claims are drawn to means of production or a process.

Therefore, the rejection of claims under 35 USC 102(b) as being anticipated by Kwon *et al* is maintained for the reasons of record.

***Claim Rejections - 35 USC § 102***

6. The rejection of claims 8,10,26,28,39, and now claims 16 and newly added claims 40-42 under 35 USC § 102 as being anticipated by Rennert *et al* (J. Exp. Med. 1996; 184:1999-2006) is maintained for the reasons of record. Applicant's arguments are substantially similar to those already presented and argued (see paragraph 4 above). Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. For the purposes of examination, the term "preparation" as currently amended is interpreted as being a product as opposed to a method of making. Furthermore, applicant is reminded that an examination on the merits has been performed on a product and not a method. Again, the product taught by Kwon *et al* appears to have the same activity of the instant product (i.e. ability to bind to a ligand) and therefore the claim limitations drawn to means of preparing the product do not necessarily impart any structurally distinct characteristics onto the product claimed.

It is noted that MPEP 2113 teaches that the product does not depend on the method of production, therefore, newly added claims 40 and 42 do not provide limitations that are deemed patentably distinct because these claims are drawn to means of production or a process.

With regard to claim 16 and 41, by applicant's own admission, Rennert *et al* teaches and cites a reference that discloses the production of an Ig fusion products in a CHO cell (see applicant's response page 13), and the use of LT-beta R-Ig fusion proteins *in vivo* (see page 13, last paragraph). These claims are anticipated because

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the process of making this product does not distinguish over the products of the prior art. Specifically, Rennert *et al* teach a product that is identical to that instantly claimed and applicant has not provided objective evidence to show structure difference between the prior art and that instantly claimed.

Therefore, the rejection of claims under 35 USC 102(b) as being anticipated by Kwon *et al* is maintained for the reasons of record.

**All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 9/27/2004.**

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1642  
December 20, 2004



**GARY NICKOL**  
**PRIMARY EXAMINER**